or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations.

(d) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

(e) The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a FONSI will be prepared. The responsible agency official examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

[62 FR 40592, July 29, 1997, as amended at 69 FR 17291, Apr. 2, 2004]

§ 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) The agency official(s) responsible for approving the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusion not to prepare an EIS for the action under consideration.

§ 25.42 Environmental impact statements.

(a) As defined by CEQ regulations (40 CFR 1508.11) and section 102(2)(C) of NEPA, an EIS should be a clear, con-cise, and detailed written statement describing:

(1) The environmental impacts of a proposed action;

(2) Any adverse effects that cannot be avoided if the action is implemented;

(3) Alternatives to the action;

(4) The relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and

(5) Any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

(b) The CEQ regulations (40 CFR 1501.7 and part 1502) describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. CEQ format and procedures for preparing EIS shall be followed.

(c) Under the conditions prescribed in 40 CFR 1502.9, the agency will prepare a supplement for a draft or final EIS and introduce the supplement into the administrative record.

§ 25.43 Records of decision.

(a) In cases requiring environmental impact statements, at the time of its decision, the agency shall prepare a concise public record of decision.

(b) The record of decision shall:

(1) State what the decision was;

(2) Identify and discuss alternatives considered by the agency in reaching its decision;

(3) State whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why not; and

(4) Summarize the program for monitoring and enforcing the practicable means adopted to avoid or minimize the environmental harm.

§ 25.44 Lead and cooperating agencies.

For actions requiring the preparation of an EIS, FDA and other affected Federal agencies will agree which will be the lead agency and which will be the cooperating agencies. The responsibilities of lead agencies and cooperating agencies are described in the CEQ regulations (40 CFR 1501.5 and 1501.6, respectively). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate